

REMARKS

Applicant filed an Amendment on August 2, 2006. On August 3, 2006, Applicant's counsel received a Decision from the Board of Patent Appeals and Interferences dated July 31, 2006 in the parent case, Serial No. 10/272,382, which affirmed the Examiner-in-part and reversed the Examiner-in-part, holding composition claims 6, 10, 11 and 17 as non-obvious. A copy is attached.

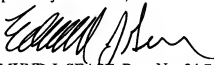
While the claims of that appeal were compound claims and composition claims, the holding may have some relevancy to the issues relating to these divided out method claims, mainly:

- "small but nutritionally effective amount" was a part of the claims at issue; and
- the opinion of non-obviousness as to the composition claims 6, 10, 11 and 17 of the parent may well apply with even more force to the method claims here at issue.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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Enclosure: Decision on Appeal

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

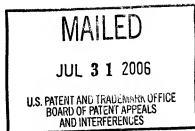
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MAHMOUD M. ABDEL-MONEM, and
MICHAEL D. ANDERSON

Appeal No. 2006-1226
Application No. 10/272,382

HEARD July 11, 2006



Before ADAMS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a 1:1 complex of an essential trace element, such as zinc or copper, and aspartic acid or glutamic acid. The examiner has rejected the claims as anticipated by or obvious in view of the prior art. We have jurisdiction under 35 U.S.C. § 134. We agree with the examiner that the claimed complex reasonably appears to have been known in the art, but we disagree that the cited references would have suggested combining it with calcium carbonate. We therefore affirm the rejection for anticipation but reverse the rejection for obviousness.

Background

Complexes of metal salts and amino acids are known in the art and useful in animal feeds, among other things. See the specification, pages 1-2. In one form, "[t]hese complexes exist as ion pairs in which the metal-amino acid comprises the cation. The counter ion (anion) is provided by a mineral acid." Page 3, lines 4-5.

The specification discloses "metal amino acid complexes in which the amino acid serves a dual role. It serves as the bidentate ligand to form a complex with the metal ion, and the counter ion to balance the charge on the cationic complex. This allows the preparation of stable crystalline complexes that contain 20-30% metal. The alpha amino dicarboxylic acids aspartic and glutamic acid are examples of suitable ligands." Id., lines 8-12.

The specification notes that

some sources make reference to compounds containing metals and aspartic or glutamic acid. . . . In the first report copper glutamate dihydrate was obtained by the slow evaporation of a solution of glutamic acid and copper nitrate (The Crystal Structure of Copper Glutamate Dihydrate, Carlo M. Gramaccioli and Richard E. Marsh, Acta Cryst., 21, 594 (1966)). The structure of the blue-green crystals was determined by x-ray crystallography. A companion paper reported the structure of the zinc glutamate dihydrate crystals obtained by the evaporation of an aqueous solution of zinc oxide in glutamic acid (The Crystal Structure of Zinc Glutamate Dihydrate, Carlo M. Gramaccioli, Acta Cryst., 21, 600 (1966)).

Page 3, lines 13-25.

Discussion

1. Claim construction

Claims 1-11 and 17 are pending and on appeal. The claims subject to each rejection will stand or fall together because Appellants have not argued them

separately. See 37 CFR § 41.37(c)(1)(vii). We will consider claims 1 and 6 to be representative. Claims 1 and 6 read as follows:

1. A 1:1 neutral complex of an essential trace element and a dicarboxylic alpha amino-acid.
6. A neutral complex of claim 1 combined with a suitable animal feed carrier selected from the group consisting of calcium hydrogen phosphate, calcium carbonate, silica, ground corn cobs, and powdered sugar or a mixture of any of the above.

Thus, claim 1 is directed to a complex of an essential trace element (e.g., zinc or copper) and a dicarboxylic alpha amino acid (glutamic acid or aspartic acid). The claimed complex is a "1:1 neutral complex," meaning that it contains one metal atom and one amino acid molecule and is electrically uncharged overall.

Claim 6 is directed to a combination of the neutral complex of claim 1 with a carrier such as calcium carbonate. While claim 6 states that the recited carriers are "suitable animal feed carriers," the claim is not limited to an animal feed composition.

2. Anticipation

The examiner rejected claims 1-5 and 7-9 under 35 U.S.C. § 102(b) as anticipated by either Gramaccioli et al.¹ or Gramaccioli.² The examiner reasoned that "the Gramaccioli references teach zinc glutamate dihydrate ($\text{ZnC}_5\text{H}_7\text{NO}_4 \cdot 2\text{H}_2\text{O}$) and copper (II) glutamate dihydrate ($\text{CuC}_5\text{H}_7\text{NO}_4 \cdot 2\text{H}_2\text{O}$). These complexes anticipate the rejected claims within the meaning of section 102." Examiner's Answer, page 3.

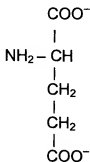
We agree with the examiner that each of the Gramaccioli references reasonably appears to disclose a 1:1 neutral complex of a metal and glutamate. The abstract of

¹ Gramaccioli et al., "The crystal structure of copper glutamate dihydrate," *Acta Cryst.*, Vol. 21, pp. 594-600 (1966)

² Gramaccioli, "The crystal structure of zinc glutamate dihydrate," *Acta Cryst.*, Vol. 21, pp. 600-605 (1966)

each of the references provides the chemical formula for the disclosed complex:

"CuC₅H₇NO₄.2H₂O" in Gramaccioli et al., "ZnC₅H₇NO₄.2H₂O" in Gramaccioli. This formula indicates that the glutamate molecule in each complex must have the following structure:



This structure corresponds to the chemical formula shown in the abstracts of the references (minus the metal atom and the two molecules of water) and also with the chemical structure shown in Figure 1 of each of the references and Figure 2 of Gramaccioli et al. (The figures leave out the hydrogen atoms shown above but the seven hydrogens shown in the chemical formula must be distributed as shown to maintain the correct valence of each of the heavier atoms.)

The chemical formula disclosed by the Gramaccioli references does not include any negatively charged counterion (anion), nor does it indicate that the zinc atom and glutamate molecule are present in anything other than a one-to-one ratio. Thus, the complexes disclosed by the Gramaccioli references appear to consist of the glutamate molecule shown above (with two negative charges) combined with one zinc or copper atom (with a charge of +2) and two water molecules (which are electrically neutral). Therefore, we agree with the examiner that each of the Gramaccioli references reasonably appears to disclose a "1:1 neutral complex of an essential trace element

[zinc or copper] and a dicarboxylic alpha amino acid [glutamate]"; each of the references therefore anticipates instant claim 1.

Appellants argue that the Gramaccioli references do not anticipate because they do not teach a utility for the disclosed metal/amino acid complexes. See the Appeal Brief, page 4, and Abdel-Monem declaration,³ ¶ 9.

We do not find this argument persuasive. "[I]t is beyond argument that no utility need be disclosed for a reference to be anticipatory of a claim to an old compound." In re Schoenwald, 964 F.2d 1122, 1124, 22 USPQ2d 1671, 1673 (Fed. Cir. 1992). See also Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1326, 75 USPQ2d 1297, 1302 (Fed. Cir. 2005) ("[A] prior art reference need not demonstrate utility in order to serve as an anticipating reference under section 102.").

Appellants argue, however, that the present case is distinguished from Schoenwald (and, presumably, more recent cases saying the same thing) in that "the Gramaccioli references are ambiguous as to their teaching. They teach only an empirical formula ($\text{CuC}_5\text{H}_7\text{NO}_4 \cdot 2\text{H}_2\text{O}$; and $\text{ZnC}_5\text{H}_7\text{NO}_4 \cdot 2\text{H}_2\text{O}$). Even the Schoenwald case says, 'the mere naming of a compound may not be enough for anticipation'." Appeal Brief, page 4.

Appellants assert that "[t]he Gramaccioli references do not provide any details on the preparation" of the disclosed compositions, such as the yield, purity or physical or chemical properties. Id.; Reply Brief, pages 2-3; Abdel-Monem declaration, ¶¶ 4 and 11. Appellants reason that "it is well known that the reaction of metal salts and amino

³ Declaration submitted under 37 CFR § 1.132 by Mahmoud M. Abdel-Monem, received October 15, 2004.

acids may provide one or more products depending on the reaction conditions used in their preparation." Appeal Brief, page 4; Abdel-Monem declaration, ¶¶ 3 and 10.

Appellants provide three examples of zinc/glutamate complexes that could form "based on the reaction conditions" (Appeal Brief, pages 5-6), implying that the Gramaccioli complexes could be any of the three shown in the Appeal Brief.

We find this argument unpersuasive. As discussed above, the chemical formula disclosed by the Gramaccioli references is consistent with a neutral complex of one atom of either copper or zinc with one molecule of glutamate. The references do not include in the chemical formula any additional counterion, nor do the disclosed formulas indicate that two molecules of glutamate were complexed with each metal atom. Thus, of the three exemplary structures set out in the Appeal Brief, only the one corresponding to the claimed complex is consistent with the Gramaccioli chemical formulas.

The Gramaccioli references teach that the disclosed complexes were formed by the simple process of mixing glutamic acid and a metal salt in aqueous solution and evaporating the water. See Gramaccioli et al., page 594 ("[c]rystals were grown by evaporation of an aqueous solution of glutamic acid and cupric nitrate") and Gramaccioli, page 600 ("[w]hite prismatic crystals of zinc glutamate dihydrate . . . form on slow evaporation of an aqueous solution of zinc oxide in glutamic acid").

Granted, this disclosure does not teach the skilled artisan precisely how much of each component to add or how quickly to evaporate the solvent. But Appellants have provided no evidence that the reference disclosures are inadequate to enable those skilled in the art to make even a minute amount of a 1:1 neutral complex of glutamate and either zinc or copper. The claims at issue are to a metal-amino acid complex per

se. and therefore are anticipated by a prior art disclosure of any amount of the claimed complex. See, e.g., SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1335, 74 USPQ2d 1398, 1403 (Fed. Cir. 2005) (claim to "[c]rystalline paroxetine hydrochloride hemihydrate" not limited to commercially significant amounts).

Appellants have not, for example, provided declaratory evidence to show that it would have required undue experimentation to make a 1:1 neutral complex of glutamate and zinc or copper. Appellants have not shown that special conditions are required to cause zinc or copper and glutamate in aqueous solution to form a 1:1 neutral complex, nor have they shown that a skilled artisan who followed the Gramaccioli guidance would not have produced such a complex. While Appellants have pointed out the lack of detailed experimental protocols in the Gramaccioli references, they have not provided evidence to show that the lack of detail renders the references nonenabling.

For the same reason, we find unpersuasive Appellants' argument that the Gramaccioli references do not anticipate because "the author[s] did not provide any independent evidence of the identity of the crystals or structure such as chemical or elemental analysis or spectroscopic analysis." Appeal Brief, page 7; Abdel-Monem declaration, ¶ 7. A prior art reference is presumed to be enabling, and the burden is on the party challenging enablement to prove it – in this context, by a preponderance of the evidence. See Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). The holding in Amgen was limited to prior art patents, but the court noted that its holding, "by logical extension," should apply to nonpatent prior art as well. Id. at 1355 n.22, 65 USPQ2d at 1416 n.22. Appellants have

provided no evidence to show that the method disclosed in the Gramaccioli references does not produce the complexes that were said to result.

Finally, Appellants argue that the Gramaccioli references do not provide "any analytical detail to determine or prove to one of ordinary skill whether these crystals were pure or homogeneous." Appeal Brief, page 6; Abdel-Monem declaration, ¶¶ 5, 6, and 8.

As discussed above, however, the instant claims are directed to metal-amino acid complexes per se. Therefore, they are anticipated by prior art disclosure of any amount of the claimed complex, in any degree of purity.

We agree with the examiner that the Gramaccioli references reasonably appear to disclose complexes within the scope of instant claim 1. Appellants have not provided sufficient evidence to the contrary. We therefore affirm the rejection of claim 1. Claims 2-5 and 7-9 fall with claim 1 because they were not argued separately.

3. Obviousness

The examiner rejected claims 6, 10, 11, and 17 under 35 U.S.C. § 103 as obvious in view of either of the Gramaccioli references and Wagner.⁴ The examiner reasoned the Wagner teaches a composition for oral hygiene containing copper salts, including copper salts of amino acids such as glutamate or aspartate, and (in the case

⁴ Wagner, U.S. Patent 4,824,661, issued April 25, 1989

of toothpaste compositions) a polishing agent that can be calcium carbonate. See the Examiner's Answer, page 4.

The examiner did not point to any disclosure in Wagner of a 1:1 neutral complex of copper and either glutamate or aspartate. However, he argued that "given the broadest reasonable interpretation of the term neutral complex, those of ordinary skill would assume that the copper salts of Wagner fall within this claim term." *Id.*, page 8.

We disagree with this interpretation of the reference. The instant specification teaches that metal amino acid complexes can take any of several forms, including 1:1 complexes "exist[ing] as ion pairs in which the cation is composed of the metal amino acid complex and the anion is that of a mineral acid" (pages 6-7) and complexes "in which the ratio of metal to amino acid is 1:2" (page 7). The examiner has provided no logical or evidentiary basis for concluding that the metal/amino acid complexes taught in Wagner were the 1:1 neutral complexes of the present claims rather than one of the other forms cited in the specification.

Although the examiner did not expressly rely on the Gramaccioli references in explaining the rejection under § 103, he did cite them in setting out the rejection. We will therefore consider an alternative basis of the rejection: that it would have been obvious to combine the copper glutamate dihydrate disclosed by Gramaccioli et al. with the calcium carbonate-containing toothpaste composition disclosed by Wagner.⁵

⁵ Wagner focuses on the suitability of copper-containing compounds in dental care compositions. The examiner has pointed to nothing in Wagner that would suggest adding zinc-containing compounds to such compositions. Therefore, to the extent that the rejection is based on the combination of Gramaccioli (zinc glutamate dihydrate) with Wagner, it is reversed for lack of motivation to combine.

We also reverse the rejection to the extent that it is based on this line of reasoning. Gramaccioli et al. discloses that crystals of copper glutamate dihydrate suitable for crystallographic studies could be formed by evaporation of an aqueous solution of cupric nitrate and glutamic acid. Page 594. The reference, however, says nothing to suggest that those crystals would be suitable for use in anything remotely related to a toothpaste composition.

As Appellants have correctly pointed out, Gramaccioli et al. does not teach a utility for the disclosed copper glutamate dihydrate crystals. While that is not an impediment to a rejection for anticipation, it does impose a burden on the examiner of articulating a reasonable basis on which a person of ordinary skill in the art would select the copper glutamate dihydrate crystals of Gramaccioli et al. for inclusion in the toothpaste composition of Wagner. The examiner has not done so and no adequate basis for motivation is apparent to us. The rejection under § 103 is reversed.

Other Issue

The instant specification states that 1:2 metal-amino acid complexes are known. See page 6, line 27, to page 7, line 8 ("The majority of the essential metal-amino acid complexes can be classified under one of two major groups. . . . The second group of metal amino acid complexes is that in which the ratio of the metal to amino acid is 1:2."). The specification also states that these complexes "must dissolve in the acid contents of the gastrointestinal tract. Under the acidic conditions at the absorption site the complexes re-equilibrate in solution to provide the 1:1 complexes and free amino acids.

Thus, the 1:2 metal-amino acid complexes are serving as costly and usually less effective pro-nutrients for the 1:1 complexes." Page 7, lines 14-18.

The statement that the "1:2 metal-amino acid complexes are serving as . . . pro-nutrients for the 1:1 complexes" appears to be an admission that the complexes defined by at least instant claim 1 were inherently anticipated by the administration of 1:2 metal-amino acid complexes in animal feed. Cf. Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1379-80, 67 USPQ2d 1664, 1668-69 (Fed. Cir. 2003) (holding compound claims inherently anticipated where evidence showed prior art compound is converted in vivo into claimed compound, even though prior art did not disclose claimed compound or show any awareness of conversion of known compound into claimed compound).

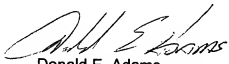
If the pending claims directed to 1:1 metal-amino acid complexes come before the examiner again, he should consider whether those claims are inherently anticipated by administration of 1:2 metal-amino acid complexes in animal feed, as evidenced by the passage quoted from the specification.

Summary

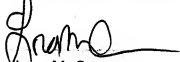
We affirm the rejection of claims 1-5 and 7-9 as anticipated by the Gramaccioli references, but reverse the rejection of claims 6, 10, 11, and 17 as obvious in view of the Gramaccioli references and Wagner.

No time period for taking any subsequent action in connection with this appeal
may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART


Donald E. Adams
Administrative Patent Judge


Eric Grimes
Administrative Patent Judge


Lora M. Green
Administrative Patent Judge

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